

Package leaflet: Information for the user

{Airbufo Forspiro, 160 micrograms/4.5 micrograms/inhalation, inhalation powder, pre-dispensed}

budesonide/formoterol fumarate dihydrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Nationally completed name] is and what it is used for
2. What you need to know before you use [Nationally completed name]
3. How to use [Nationally completed name]
4. Possible side effects
5. How to store [Nationally completed name]
6. Contents of the pack and other information

1. What [Nationally completed name] is and what it is used for

[Nationally completed name] is an inhaler that is used to treat:

- **asthma in adults and adolescents aged 12-17 years.**
- symptoms of **Chronic Obstructive Pulmonary Disease (COPD) in adults** aged 18 years and older.

It contains two different medicines: budesonide and formoterol fumarate dihydrate.

- Budesonide belongs to a group of medicines called ‘corticosteroids’. It works by reducing and preventing swelling and inflammation in your lungs.
- Formoterol fumarate dihydrate belongs to a group of medicines called ‘long-acting beta₂ adrenoceptor agonists’ or ‘bronchodilators’. It works by relaxing the muscles in your airways. This helps you to breathe more easily.

Asthma

[Nationally completed name] can be prescribed for asthma in two different ways.

- a) Some people are prescribed two asthma inhalers. [Nationally completed name] and a separate “reliever inhaler”.

- They use [Nationally completed name] every day. This helps to prevent asthma symptoms from happening.
 - They use their “reliever inhaler” when they get asthma symptoms, to make it easier to breathe again.
- b) Some people are prescribed [Nationally completed name] as their only asthma inhaler.
- They use [Nationally completed name] every day. This helps to prevent asthma symptoms from happening.
 - They also use [Nationally completed name] when they need extra doses for relief of asthma symptoms, to make it easier to breathe again. They do not need a separate inhaler for this.

Chronic obstructive pulmonary disease (COPD)

[Nationally completed name] can also be used to treat the symptoms of COPD in adults. COPD is a long-term disease characterised by continuous breathing difficulties caused by narrowed lung airways, often accompanied with coughing and phlegm. It is often caused by cigarette smoking.

2. What you need to know before you use [Nationally completed name]

Do not use [Nationally completed name] if:

- You are allergic to budesonide, formoterol, or the other ingredient of this medicine, which is lactose (which contains small amounts of milk proteins).

Warnings and precautions

Talk to your doctor or pharmacist before using [Nationally completed name] if:

- You are diabetic.
- You have a lung infection.
- You have high blood pressure or you have ever had a heart problem (including an uneven heartbeat, a very fast pulse, narrowing of the arteries or heart failure).
- You have problems with your thyroid or adrenal glands.
- You have low levels of potassium in your blood.
- You have severe liver problems.

Contact your doctor if you experience blurred vision or other visual disturbances.

Other medicines and [Nationally completed name]

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

In particular, tell your doctor or pharmacist if you are using any of the following medicines:

- Beta-blocker medicines (such as atenolol or propranolol for high blood pressure), including eyedrops (such as timolol for glaucoma).
- Medicines for a fast or uneven heart beat (such as quinidine, disopyramide, procainamide).
- Medicines to treat allergies, also called antihistamines, like terfenadine.
- Oxytocin, a medicine to facilitate childbirth.

- Procarbazine, a medicine to treat cancer.
- Medicines like digoxin, often used to treat heart failure.
- Diuretics, also known as ‘water tablets’ (such as furosemide). These are used to treat high blood pressure.
- Corticosteroids (such as prednisolone). These are used to treat inflammation or prevent organ transplant rejection.
- Xanthine medicines (such as theophylline or aminophylline). These are often used to treat asthma.
- Other medicines to widen airways, also called bronchodilators (such as salbutamol).
- Medicines to treat depression, also called tricyclic anti-depressants (such as amitriptyline) and the anti-depressant nefazodone.
- Medicines to treat mental disorders, nausea or vomiting, called phenothiazine medicines (such as chlorpromazine and prochlorperazine).
- Medicines to treat fungal infections (such as ketoconazole, itraconazole, voriconazole, posaconazole) and bacterial infections (such as clarithromycin and telithromycin, furazolidone).
- Medicines for Parkinson’s disease (such as levo-dopa).
- Medicines for thyroid problems (such as levo-thyroxine).
- Ritonavir, cobicistat (medicines to treat HIV infections). The effects of [Nationally completed name] may be increased and your doctor may wish to monitor you carefully.

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before using [Nationally completed name].

Also tell your doctor or pharmacist if you are going to have a general anaesthetic for an operation or for dental work.

Pregnancy, breast-feeding and fertility

- If you are pregnant, or planning to get pregnant, talk to your doctor before using [Nationally completed name] - do not use [Nationally completed name] unless your doctor tells you to.
- If you get pregnant while using [Nationally completed name], do not stop using [Nationally completed name] but talk to your doctor immediately.
- If you are breast-feeding, talk to your doctor before using [Nationally completed name].

Driving and using machines

[Nationally completed name] has no or negligible effect on your ability to drive or to use tools or machines.

[Nationally completed name] contains lactose

[Nationally completed name] contains lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before using this

medicine. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant.

The excipient lactose contains small amounts of milk proteins, which may cause allergic reactions.

3. How to use [Nationally completed name]

- Always use [Nationally completed name] exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- It is important to use [Nationally completed name] every day, even if you have no asthma or COPD symptoms at the time.
- If you are using [Nationally completed name] for asthma, your doctor will want to regularly check your symptoms.

If you have been taking corticosteroid tablets for your asthma or COPD, your doctor may reduce the number of tablets that you take, once you start to use [Nationally completed name]. If you have been taking oral corticosteroid tablets for a long time, your doctor may want you to have blood tests from time to time. When reducing oral corticosteroid tablets, you may feel generally unwell even though your chest symptoms may be improving. You might experience symptoms such as a stuffy or runny nose, weakness or joint or muscle pain and rash (eczema). If any of these symptoms bother you, or if symptoms such as headache, tiredness, nausea (feeling sick) or vomiting (being sick) occur, please contact your doctor immediately. You may need to take other medicine if you develop allergic or arthritic symptoms. You should speak to your doctor if you are concerned as to whether you should continue to use [Nationally completed name].

Your doctor may consider adding corticosteroid tablets to your usual treatment during periods of stress (for example, when you have a chest infection or before an operation).

Important information about your asthma or COPD symptoms

If you feel you are getting breathless or wheezy while using [Nationally completed name], you should continue to use [Nationally completed name] but go to see your doctor as soon as possible, as you may need additional treatment.

Contact your doctor immediately if:

- Your breathing is getting worse or you often wake up at night with asthma.
- Your chest starts to feel tight in the morning or your chest tightness lasts longer than usual.

These signs could mean that your asthma or COPD is not being properly controlled and you may need different or additional treatment immediately.

Asthma

[Nationally completed name] can be prescribed for asthma in two different ways. The amount of [Nationally completed name] to use and when to use it depends on how it has been prescribed for you.

- a) If you have been prescribed [Nationally completed name] and a separate reliever inhaler, read the section called “a) Using [Nationally completed name] and a separate reliever inhaler”.
- b) If you have been prescribed [Nationally completed name] as your only inhaler, read the section called “b) Using [Nationally completed name] as your only asthma inhaler”.

a) Using [Nationally completed name] and a separate reliever inhaler.

Use your [Nationally completed name] every day. This helps to prevent asthma symptoms from happening.

Adults (18 years and above)

- The usual dose is 1 or 2 inhalations, twice a day.
- Your doctor may increase this to 4 inhalations, twice a day.
- If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.

Adolescents (12 to 17 years)

- The usual dose is 1 or 2 inhalations, twice a day.
- If your symptoms are well controlled, your doctor may ask you to take your medicine once a day.

[Nationally completed name] is not recommended to be used in children who are younger than 12 years.

Your doctor (or asthma nurse) will help you to manage your asthma. They will adjust the dose of this medicine to the lowest dose that controls your asthma. However, do not adjust the dose without talking to your doctor (or asthma nurse) first.

Use your separate “reliever inhaler” to treat asthma symptoms.

Always keep your “reliever inhaler” with you to use when you need it. Do not use [Nationally completed name] to treat asthma symptoms – use your reliever inhaler.

b) Using [Nationally completed name] as your only asthma inhaler.

Only use [Nationally completed name] in this way if your doctor has told you to and if you are aged 12 or above.

Use your [Nationally completed name] every day. This helps to prevent asthma symptoms from happening. You can take:

- 1 inhalation in the morning and 1 inhalation in the evening
or
- 2 inhalations in the morning
or
- 2 inhalations in the evening.

Your doctor may increase this to 2 inhalations twice a day.

Also use [Nationally completed name] as a ‘reliever inhaler’ to treat asthma symptoms when they happen.

- If you get asthma symptoms, take 1 inhalation and wait a few minutes.

- If you do not feel better, take another inhalation.
- Do not take more than 6 inhalations at a single time.

Always keep your [Nationally completed name] with you, so you can use it when you need it.

A total daily dose of more than 8 inhalations is not normally needed. However, your doctor may allow you to take up to 12 inhalations a day for a limited period.

If you regularly need to use 8 or more inhalations a day, make an appointment to see your doctor or nurse. They may need to change your treatment.

Do not use more than 12 inhalations in total in 24 hours.

If you are doing exercise and you get asthma symptoms, use [Nationally completed name] as described here. However, do not use [Nationally completed name] just before exercise to stop asthma symptoms from happening.

Chronic Obstructive Pulmonary Disease (COPD)

- Only to be used by adults (aged 18 years and above).
- The usual dose is 2 inhalations twice a day.

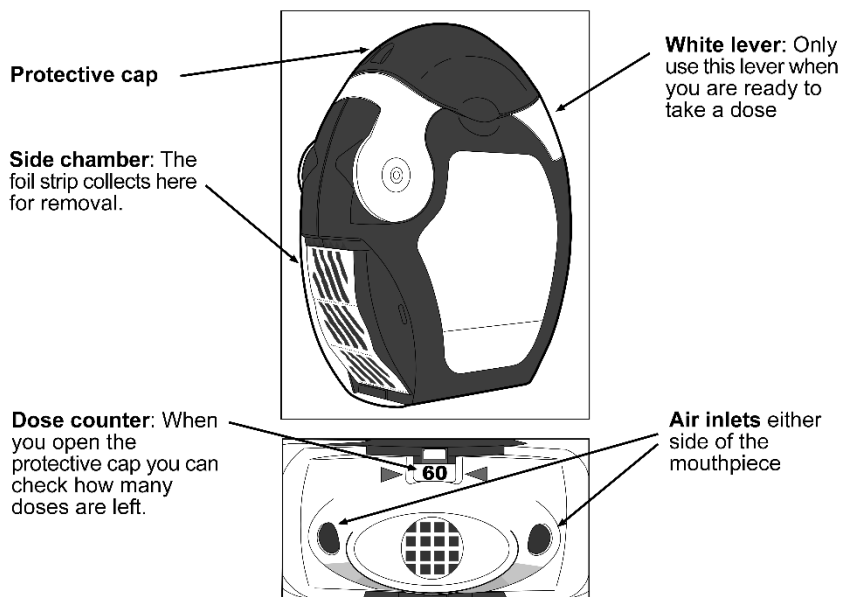
Your doctor may also prescribe other medicines to widen your airways, also called bronchodilator medicines (such as tiotropium or ipratropium bromide) for your COPD disease.

Instructions for use

Your doctor, nurse or pharmacist should demonstrate how to use the inhaler and should check your use regularly.

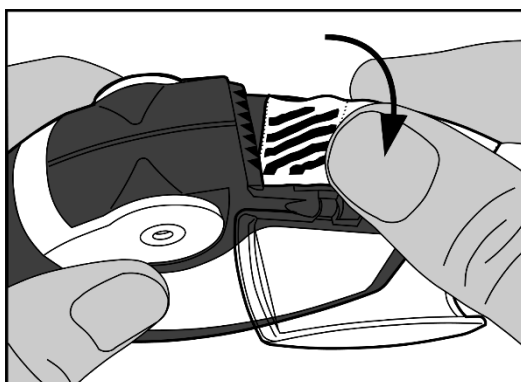
The inhaler contains 60 doses of powder medicine in a coiled strip of foil. It has a dose counter which shows you how many doses you have remaining counting down from 60 to 0. When you have reached the last 10 doses the numbers will be on a red background.

The inhaler is not refillable – please dispose of the inhaler when it is empty and replace it with a new one.



Before using the inhaler

- Open the transparent side chamber door.
- Remove the foil strip from the side chamber by carefully tearing away the full length of strip against the 'teeth' of the side chamber as shown below. **Do not pull or tug** on the strip.



- Close the side chamber door and dispose of the used strip.

Important:

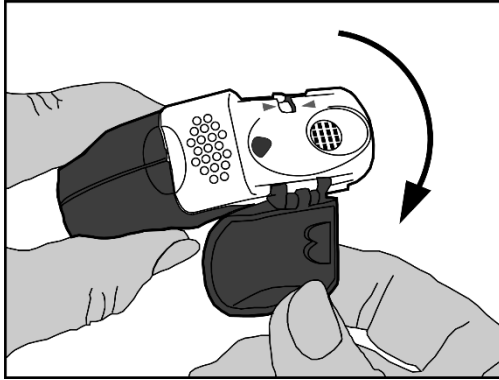
As you use the inhaler the side chamber will gradually fill up with used strip. The foil strips with **black bars don't contain medicine**. Eventually the numbered sections of the strip will appear in the side chamber.

Do not let more than 2 sections of foil strip build up in the side chamber as they may cause the inhaler to jam. Tear the strip away carefully as shown above, and dispose of it safely.

Using the inhaler

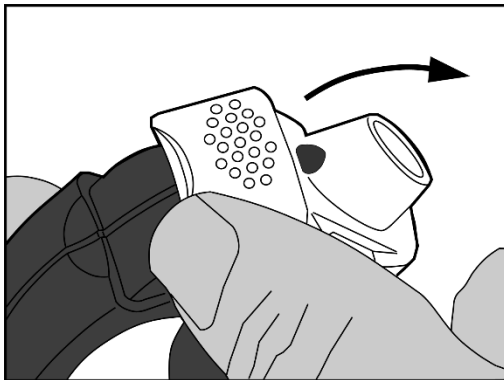
Hold the inhaler in your hands as seen in the pictures.

1. Open

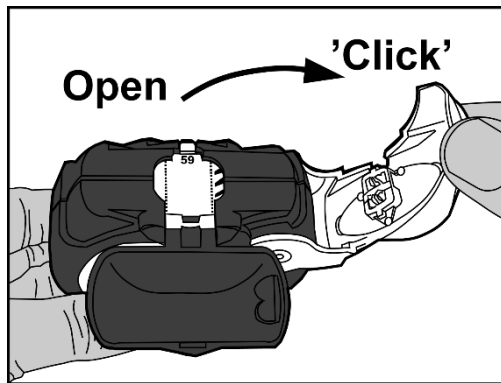


- **Open** the protective **cap downwards** to reveal the mouthpiece.
- Check the dose counter to see how many doses are left.

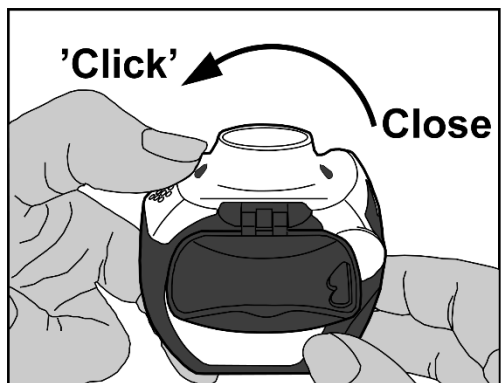
2. Prepare the dose



- **Lift up** the edge of the **white lever**. Make sure the side chamber is closed.
Remember: Only operate the white lever when you are ready to inhale a dose of your medicine. If you play with the white lever, you will waste doses.



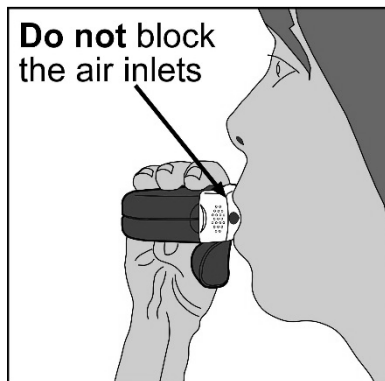
- **Open:** Move the **white lever fully over** as far as it will go and **until it clicks**. This action moves a new dose into position with the number at the top.



- **Close:** Afterwards **close** the **white lever fully** so that it **clicks** back into its original position. The inhaler is now ready for immediate use.

3. Inhale

- Away from the inhaler mouthpiece, breathe out as much as is comfortable. **Never breathe directly into** the inhaler as this could affect the dose.
- Hold the inhaler level with the **protective cap pointing downwards**.
- Close your lips firmly around the mouthpiece.
- **Breathe** in as **deeply** and as hard as possible through the inhaler, not through your nose.



- Remove the inhaler from your mouth and **hold your breath for 5-10 seconds** or as long as you can without causing discomfort.
- Afterwards, breathe out slowly, **but not into the inhaler**.
- Close the protective cap over the mouthpiece.
- Rinse your mouth with water and spit it out. This may help to prevent you from getting fungal infection in the mouth and becoming hoarse.

Cleaning

- Wipe the outside of the mouthpiece with a clean, dry tissue if necessary.
- Do not attempt to take the inhaler apart to clean it or for any other purpose!
- Do not use water or wet wipes to clean the inhaler parts as dampness can affect the dose!
- Never insert a pin or other sharp objects into the mouthpiece, or any other part, as this could damage the inhaler!

If you use more [Nationally completed name] than you should

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not exceed your prescribed dose without seeking medical advice.

The most common symptoms that may occur if you use more [Nationally completed name] than you should are trembling, headache or a rapid or irregular heartbeat.

If you forget to use [Nationally completed name]

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Do **not** take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If either of the following happen to you, stop using [Nationally completed name] and talk to your doctor immediately:

- Swelling of your face, particularly around your mouth (tongue and/or throat and/or difficulty swallowing) or hives together with difficulty breathing (angioedema) and/or sudden feeling of faintness. This may mean that you are having an allergic reaction. This happens rarely (may affect up to 1 in 1,000 people).
- Sudden acute wheezing or shortness of breath immediately after using your inhaler. **If either of these symptoms occur, stop using your [Nationally completed name] straightaway and use your ‘reliever’ inhaler. Contact your doctor immediately as you may need to have your treatment changed.** This happens very rarely (may affect up to 1 in 10,000 people).

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Palpitations (awareness of your heart beating), trembling or shaking. If these effects occur, they are usually mild and usually disappear as you continue to use [Nationally completed name].
- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using your [Nationally completed name].
- Mild sore throat, coughing and a hoarse voice.
- Headache.
- Pneumonia (infection of the lung) in COPD patients.

Tell your doctor if you have any of the following while taking [Nationally completed name], they could be symptoms of a lung infection:

- Fever or chills.
- Increased mucus production, change in mucus colour.
- Increased cough or increased breathing difficulties.

Uncommon (may affect up to 1 in 100 people)

- Feeling restless, nervous or agitated.
- Disturbed sleep.
- Feeling dizzy.
- Blurred vision.
- Nausea (feeling sick).
- Fast heartbeat.
- Bruising of the skin.
- Muscle cramps.
- Aggression.
- Anxiety.

Rare (may affect up to 1 in 1,000 people)

- Rash, itching.
- Bronchospasm (tightening of the muscles in the airways which causes wheezing). If the wheezing comes on suddenly after using [Nationally completed name] stop using [Nationally completed name] and talk to your doctor immediately.
- Low levels of potassium in your blood.
- Uneven heartbeat.

Very rare (may affect up to 1 in 10,000 people)

- Depression.
- Changes in behaviour, especially in children.
- Chest pain or tightness in the chest (angina pectoris).
- An increase in the amount of sugar (glucose) in your blood.
- Taste changes, such as an unpleasant taste in the mouth.
- Changes in your blood pressure.
- Weight gain, moon-shaped face, weakness, abdominal obesity (Cushing's syndrome).

Inhaled corticosteroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. The effects include:

- changes in bone mineral density (thinning of the bones)
- cataract (clouding of the lens in the eye)
- glaucoma (increased pressure in the eye)
- a slowing of the rate of growth of children and adolescents
- an effect on the adrenal gland (a small gland next to the kidney).
- Cushingoid features
- increased susceptibility to infections and impairment of the ability to adapt to stress may also occur.

These effects are much less likely to happen with inhaled corticosteroids than with corticosteroid tablets.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally completed name]

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the carton or on the label of your inhaler after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Nationally completed name] contains

- The active substances are budesonide and formoterol fumarate dihydrate. Each inhaled dose contains 160 micrograms of budesonide and 4.5 micrograms of formoterol fumarate dihydrate, this corresponds to a metered dose (pre-dispensed dose contained in the blister) of 194.7 micrograms of budesonide and 6.1 micrograms of formoterol fumarate dihydrate.
- The other ingredient is lactose monohydrate (contains milk proteins).

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] is a red/white, plastic inhaler containing your medicine. Each inhaler contains an OPA/Al/PVC-Al blister with 60 doses of inhalation powder, pre-dispensed. The inhalation powder is white to off-white or slightly yellow of colour with no agglomerates.

[Nationally completed name] is available in packs of 1, 2 or 6 inhaler(s), each with 60 doses.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

<This medicinal product is authorised in the Member States of the EEA under the following names:>

[To be completed nationally]

This leaflet was last revised in 2021-10-21.

[To be completed nationally]